

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

JUDY WETHINGTON, et al.,	:	NO. 1:01-CV-00441
	:	
	:	
Plaintiffs,	:	
	:	<b>ORDER</b>
v.	:	
	:	
PURDUE PHARMA LP, et al.,	:	
	:	
	:	
Defendants.	:	

This matter is before the Court on Plaintiffs' Motion to Reconsider Order Denying Class Certification (doc. 119), Purdue Defendants' Opposition (doc. 122), Abbott Defendants' Opposition (doc. 123), and Plaintiffs' Reply (doc. 124). Subsequently, Defendants filed a Motion to Strike Exhibit "A" to Plaintiffs' Reply Memorandum (doc. 125), a Supplemental Authority in Support of their Opposition (doc. 126), which Plaintiffs Opposed (doc. 127), and Defendants replied (doc. 128).

Plaintiffs ask the Court to reconsider its September 30, 2003 Order denying Plaintiffs' Motion to Certify the litigation as a class action (doc. 117). Plaintiffs base their request on the theory that they have obtained new evidence that OxyContin is a defective product, and that Defendants failed to warn doctors about the highly addictive nature of the drug (Id.). Plaintiffs proffer the Amended Complaint in a Connecticut whistleblower action by a former researcher for Purdue, Dr. Marek Zakrzewski, which alleges

that OxyContin is more addictive than an ordinary physician would expect (Id.). Plaintiffs posit that questions about the defective nature of the drug and inadequate warnings can be resolved in a single adjudication for the proposed class (Id.). Plaintiffs further argues that the Court improperly reviewed the merits of their claims in denying class certification (Id.).

Purdue Defendants respond that Plaintiffs' Motion is untimely, that it fails to establish the criteria upon which courts reconsider class certification rulings, that there has been no change in the substantive or procedural law, and that the bulk of Plaintiffs' evidence is not new, as it was already submitted to the Court prior to the October 1, 2003 Order (doc. 122). Purdue Defendants argue that the only new evidence proffered, a Drug Enforcement Agency report, does not pertain to putative class members (Id.). However, in response to Dr. Zakrzewski's claims, Purdue proffers the affidavit of Dr. Glenn Van Buskirk, refuting their scientific validity (Id.).

Abbott Defendants similarly respond that Plaintiffs have not shown a reason to modify the Court's Order, that Plaintiffs' proposed common issues are trumped by individual considerations, and that the Court did not impermissibly delve into the merits of the underlying claims (doc. 123). Abbott Defendants further argue that under Fed. R. Civ. P. 23(1), an amendment of an Order denying class certification is only appropriate where changed circumstances warrant modification, and that no new developments have occurred (Id.). Abbott concludes that none of the "new" information offered

by Plaintiffs supports any claim against Abbott (Id.).

Plaintiffs reply they possess new evidence in the form of the DEA Report that states that OxyContin is highly addictive (doc. 124). They posit that such pronouncement directly contradicts Defendants' representations that OxyContin rarely causes addiction (Id.). Plaintiffs argue that Defendants wrongly assert that the alleged product defects do not affect members of the class, and that Plaintiffs seek to represent all those who first received the drug by prescription (Id.).

Plaintiffs rely heavily on Dr. Zakrzewski's Amended Complaint, filed subsequent to the Court's October 1, 2003 Order denying class certification (Id.). Plaintiffs state that Zakrzewski's Complaint alleges that Defendants purposely hid from the Food and Drug Administration ("FDA") and the medical community that OxyContin was defective because of inconsistent rates of absorption (Id.). According to Zakrzewski, Defendants' use of a faster dissolving form of oxycodone HCL, from that which was approved by the FDA, could cause overdosing and lead to addiction (Id.).

Plaintiffs argue they timely filed their request for reconsideration, because class certification orders are conditional and are always subject to review, citing Anderson v. Douglas & Lomason Company, 122 F.R.D. 502, 504 (N.D. Miss. 1988) (Id.). They argue further that their new evidence demonstrates predominate issues of fact regarding FDA disclosures and Defendants' compliance with safety requirements (Id.). Relying upon In re Copley

Pharmaceutical, Inc., 158 F.R.D. 485 (D. Wyoming 1994), Plaintiffs argue that if the high incidence of addiction is caused by an undisclosed manufacturing defect, variable dissolution rates, then class certification is appropriate (Id.). Plaintiffs posit that by submitting a counter affidavit, Purdue has acknowledged at a minimum a difference of opinion regarding the substance of Dr. Zakrzewski's allegations (Id.). Plaintiffs conclude that the new evidence they have proffered supports holding the class certification order in abeyance, and the Court should permit the parties to explore such evidence further before affirmatively ruling that class certification is inappropriate (Id.).

Defendants filed their Motion to Strike on January 14, 2004, attacking the Amended Complaint of Dr. Zakrzewski as inadmissible hearsay of no relevance to the predominance of individual issues that preclude class certification (doc. 125). As a supplemental authority, Defendants filed the recently issued Order of Judge Reeves of the Eastern District of Kentucky, who granted summary judgment for Defendants on all claims, dismissing the action with prejudice (doc. 126 citing Foister v. Purdue Pharma, No. 01-268-DCR (Judgment, Memorandum Opinion and Order, E.D. Ky, Dec. 30, 2003)). Plaintiffs responded, primarily relying yet again upon the Zakrzewski Complaint, while also introducing a January 5, 2003 opinion in patent litigation between Purdue and Endo Pharmaceuticals, Inc., and a December 2003 report of the General Accounting Office ("GAO") to Congress concerning OxyContin abuse (doc. 127). Defendants replied on February 9, 2004, that the

Zakrzewski case was voluntarily dismissed on February 3, 2004, and as such should not be relied upon in any manner (doc. 128). Defendants further indicated that the GAO report provides no basis for the Court to reconsider its denial of class certification because it pertained to videos available only after eight of ten of class representatives had already been prescribed the drug, and the videos were only distributed to a fraction of the physicians nationwide who prescribe the drug (Id.). Finally, Defendants argue that the patent litigation has been appealed, and has nothing to do with the safety or efficacy of the drug, FDA approval, or information provided to physicians (Id.).

As an initial matter, the Court finds that contrary to Defendant Purdue's position, Plaintiffs' Motion is not untimely. Anderson v. Douglas & Lomason Company, 122 F.R.D. 502, 504 (N.D. Miss. 1988). However, upon review of the parties' arguments, the Court does not find an adequate basis to reconsider its October 1, 2003 Order denying class certification. Fed. R. Civ. P. 23(c)(1) provides that an amendment of an order denying class certification is appropriate only where changed circumstances warrant such a modification. The Court is not impressed with Plaintiffs' reliance on the unsubstantiated and voluntarily dismissed assertions of a disgruntled employee, nor with Plaintiffs' tardily tweaked theory that Defendants misled doctors by failing to warn them of product defects. Contrary to Plaintiffs' argument, often courts must look beyond the pleadings to the proof that will be necessary at trial in order to properly evaluate a motion to certify. General Tel.

Co. Of Southwest v. Falcon, 457 U.S. 147, 160 (1982), Coopers & Lybrand v. Livesay, 437 U.S. 463, 469 n.12 (1978), Szabo v. Bridgeport Machs., Inc., 249 F.3d 672, 678 (7<sup>th</sup> Cir. 2001) cert. denied, 534 U.S. 951 (2001). The Court finds well-taken Defendants' position that Plaintiffs have not cited to any case in which a district court withdrew its class certification ruling based upon a party's claim that a court improperly considered the merits in reaching its decision. Moreover, it is indeed ironic that Plaintiffs argue that the Court acted improperly in reaching merit-based issues that Plaintiffs themselves raised in an effort to identify a common issue.

The Court further finds Plaintiffs' argument lacking in merit that they have new evidence based on the October 2003 DEA document stating that "OxyContin is highly addictive. Abusers can easily compromise the controlled release formulation for a powerful morphine-like high." As the Court noted in its Order, like any prescription drug, OxyContin can be abused. This fact, however, does not persuade the Court that a common issue exists as to the putative class, who receive the drug pursuant to a valid prescription under the care of a physician. The Court already indicated that it finds well-taken Defendants' position that any crushing of the product would likely constitute intentional product misuse, thus barring a products liability claim (doc. 117). The Court further finds persuasive Defendants' present arguments that Plaintiffs' cited language in the patent dispute with Endo Pharmaceuticals, and in the GAO Report provide no basis for class

certification of this matter.

In conclusion, the Court does not find that Plaintiffs have proffered persuasive new information justifying reconsideration pursuant to Rule 23(c)(1). Accordingly, the Court DENIES Plaintiffs' Motion to Reconsider Order Denying Class Certification (doc. 119). The Court further DENIES Defendants' Motion to Strike the Zakrzewski Complaint, which the Court has considered but found unpersuasive, and further, which was voluntarily dismissed on February 3, 2004.

SO ORDERED.

Dated: February 12, 2004

s/S. Arthur Spiegel  
S. Arthur Spiegel  
United States Senior District Judge